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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

NO. – 74-501

WYETH LABORATORIES, a division of American Home Products Corporation, a Delaware corporation,
Petitioner,

V.

EPIFANIO REYES, individually and as next friend of Anita Reyes, a minor,
Respondent.

RESPONDENT'S ANSWER TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH DISTRICT

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November 25, 1974

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The respondent prays that the petition for writ of certiorari to review the opinion and judgment of the United State Court of Appeals for the Fifth Circuit rendered in these proceedings, on July 31, 1974, BE DENIED.

JURISDICTION

The Petitioner predicates its Petition for a Writ of Certiorari upon two points, neither of which has heretofore been raised before the Federal District Court or the Fifth Circuit Court of Appeals.

Rule 23(1) (c) states that the Supreme Court limits the Petitioner to the points raised in the petition, and these points must properly arise in the record (Tyrrell vs. District of Columbia, 243 U.S. 1), and must have been urged and briefed below, (California vs. Taylor, 353 U.S. 553; Lawn vs. United States, 355 U.S. 339 and Neely vs. Eby Construction Co., 386 U.S. 317)

QUESTIONS PRESENTED

1. Whether by enactment of the Federal Food, Drug and Cosmetic Act, as amended, and the Public Health Service Act, as amended, Congress has so pre-empted the field applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of the case solely on the basis of local tort law.

2. Whether the Court of Appeals contravened the public health policy of the State of Texas and of the United States and erred in its application of Texas law in holding, in the face of statutorily expressed public policy of Texas to the contrary and in disregard of the holding in the only Texas case in point, that under Texas law, a manufacturer of a prescription drug, used to immunize large segments of the population against paralytic polio is required to warn the ultimate consumer of the dangers of the vaccine even though admittedly adequate warnings have been given to the physician-administrators of the public health facility dispensing the drug.

STATEMENT OF FACTS

On May 8, 1970, in Mission, Texas, which is located in the most southern part of the State in an area referred to as the Rio Grande Valley, eight-month-old Anita Reyes was taken by her mother--a woman with a seventh-grade education--for her immunizations at a public health clinic where Mrs. Reyes had taken her other twelve children.

While at the clinic this eight-month-old child received a D.P.T. shot and was fed trivalent oral polio vaccine which contained Type I, Type II, and Type III live polio virus. She was given her polio vaccine in connection with a continuing immunization program which is carried on in these clinics throughout the year. At no time was Anita's mother warned or informed of any risks involved in the taking of the vaccine in May. In fact the public health nurse who administered the vaccine, while aware of the risk, deliberately avoided advising her of any risk.

About fourteen days after receiving her polio vaccine, Anita developed a fever. On May 23 she was admitted to the Hospital with a diagnosis of paralytic polio Type I. Since then she has been permanently paralyzed from the waist down, is not able to walk, has atrophy of her left arm, and cannot control her bladder of bowel movements.

Six years before Anita was ever vaccinated, to-wit, in July, 1964, because of the continuing occurrence of cases of paralytic disease in association with the administration of the oral poliomyelitis (Sabin) vaccine, a special advisory committee had been named by the Surgeon General of the Public Health Service to make a study of the problem. After studying 123 cases the committee categorized fifty-seven as being compatible with vaccine-induced disease using the following criteria for compatible cases: (Emphasis added.)

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine type in question and with an onset of paralysis not sooner than six days after the feeding.

2. Significant residual lower-motor-neuron paralysis.

3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.

4. No evidence of upper-motor neuron disease, definite sensory loss, or progression of recurrence of paralytic illness one month or more after onset.

These compatible cases were further subdivided into "probable" and "possible" cases employing the following guidelines for "probable" cases:

1. Evidence of fever at onset of paralysis.

2. History of systemic illness preceding the development of paralysis.

3. Clinical evidence of meningeal involvement manifested either by nuchal rigidity of cerebrospinal fluid cell count greater than 10 cells per cubic milliliter.

The record also shows that prior to the widespread use of Sabin vaccine, a Committee on Poliomyelitis Control meeting at the Center for Disease Control in Atlanta, Georgia, in January, 1961, had made reports containing the following precautions:

"Because of the unique nature of live polio-virus vaccine, with its capacity to spread the virus in a limited manner to nonvaccinated persons, the Committee cannot make

recommendations for manufacture without expressing concern about the manner in which it may be used. The seriousness of this responsibility can be illustrated, for example, by the known potentiality of reversion to virulence of live polio-virus vaccine strains, and the possible importance of this feature in the community if the vaccine is improperly used."

"5. Seasonal Limitations and Geographic Considerations

Mention has been made that in the United States the optimal time for the administration of the oral vaccine is from November 1 until May 31. For the southern tier of States, in which the poliomyelitis season as well as the season for other enterovirus infections has been recognized as starting prior to June 1, a shorter period is preferable, I. E., November 1 to March 31."

By its findings the jury concluded that Anita Reyes met all of the afore-mentioned guidelines set out by the committee for guidance of the medical profession as being a "probable" vaccine associated case, and that she was vaccinated at the wrong time of the year.

It is interesting to note that in 1964 the Center for Disease Control in its Surveillance Summary reported on Page 3 thereof that out of 56 case reports of paralytic polio for that year 20 were vaccine associated. (Page 3, 1964 Surveillance Report) (Emphasis added.) This report was available 4 years before Dr. Bierly, Wyeth's Vice-President, prepared the package insert in 1968.

The only manner in which Wyeth warned the consumers of the vaccine was by using said package insert and quoting some unrelated parts of the Surgeon General's Committee's Report. The only reference in the insert to the seasonal limitations

was as follows: "preferably should be administered during the non-polio season, if such exists in the area where the vaccine is to be used."

Dr. Ramiro R. Casso, a graduate engineer and medical doctor, the doctor who actually treated Anita Reyes, concluded that Anita Reyes met all of the criteria for both compatible and probable vaccine-caused case and that, therefore, he was of the opinion that her polio was caused by the vaccine. After studying all the statistics, he estimated that one out of every 290,000 individuals vaccinated with Sabin vaccine would contract polio from the vaccine, and further that Anita Reyes had received her vaccine during the polio season. Dr. Casso further testified that in connection with polio vaccines he had changed his system of immunizing patients because of the risks involved. He agrees that "primary emphasis should be given in all communities during their first year of life, however, in a special manner." He stated that "you have to be very much aware of the fact that the resistance that a new born has is high and it drops in the first eight to ten months of life, but they should not be immunized with live virus (Sabin) vaccine because they are less resistant." Instead of giving them oral polio vaccine (live virus), he states, "I am now giving the other one (Salk) which I know cannot cause----has no association with paralytic polio." He testified that he administers the Salk (dead virus) vaccine during their first year of life to kick up the antibodies. Then it would be safe to use the oral vaccine to give them permanent immunity. He stated further that "during their first year of life we're taking a risk by subjecting them to the oral vaccine." Regarding Sabin vaccine, he stated, "the only question that has been raised, as you know, are those of vaccine association of paralytic disease; but there has never been any question raised about the efficacy of the other vaccine, of the Salk vaccine, which was a killed virus vaccine." Local pediatricians in the County were also administering Salk vaccine (dead virus) to build up the children's antibodies prior to feeding them live virus.

Wheth offered the testimony of five doctors who had never seen Anita Reyes and had seen her hospital records only about one month prior to the trial, that is, two years after her vaccination. Each of these doctors testified that because of the opinion by Dr. Nakano that the virus was "probably wild", and the fact that seven other cases of polio had been reported from the County, Anita Reyes in their opinion had contracted polio from a wild or natural virus. Dr. Nakano admitted, however, he was only making an "educated guess". The sixth doctor presented by Wyeth was Dr. Miller, who expressed a similar opinion based on the same reasons, although he had seen Anita one time in the hospital.

It is interesting to note from the record that four of the seven cases in the Rio Grande Valley occurred after Anita's case and none had occurred in Mission, a city of 12,000, at the time.

Dr. Fox, Associate Dean, School of Public Health, and Professor of Epidemiology, University of Washington, one of the doctors who testified for Wyeth, stated that there was a risk in taking the vaccine and that the recipient should be warned of this risk. He recognized also that some of the polio cases reported had been caused by the vaccine, and that the polio season in this area was in May and June. (Emphasis added.) Dr. Dickerson, Director of Public Health for Texas, and Dr. Melneck likewise stated that in the Rio Grande Valley the polio season was May and June.

Dr. Nathanson, Professor of Epidemiology at John Hopkins and Editor of the American Journal of Epidemiology, another witness for Wyeth, who has published close to 50 papers dealing with research of virus infections of the nervous systems, also recognized that there were cases caused by the vaccine and that the risk of contracting polio from the vaccine was one case for fewer than 1 million persons vaccinated. (Emphasis added.) However, he also testified that if the two cases in the Valley (which includes Anita's case--both children

being under one year of age), in which the children had contracted polio after ingesting the vaccine were actually caused by the vaccine then the risk in this area was one out of 5,000 children. In addition Dr. Nathanson recognized the fact that it was common knowledge throughout the drug industry that the majority of the vaccine is sold to public health departments and sent to local public health clinics for use in mass administrations or community clinics where volunteers go and help give these vaccines; where no doctors are present; and where the same vial of vaccine is used to give drops of vaccine to as many as ten different babies.

DISCUSSION OF FIRST POINT

The first point submitted by Petitioner is that the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040 (1938), as amended, 21 U.S.C. Sec. 301, et seq. (1970), and the Public Health Service Act, 58 Stat. 702 (1944), as amended, 42 U.S.C. Sec. 262, et seq. (1970) has so pre-empted the field of law applicable to the labeling of prescription biological drug products that it was error for the courts below to dispose of the case solely on the basis of local tort law.

Both contentions are completely without merit. In the first place, the Federal Food, Drug and Cosmetic Act is a criminal statute. U.S. vs. Lee, D. C. Wis. 1941, 40 F. Supp. 801, reversed on other grounds 131 F. 2d 464, 143 A.L.R. 1451. It was intended to protect consumers from misleading claims in connection with sale of certain products and from hazards of adulteration, mislabeling and misbranding. U.S. vs. Kuch, D.C.D.C. 1968, 288 F. Supp. 439, 35 A.L.R. 3rd 922. In enacting the Food, Drug and Cosmetic Act, the Congress had no intention to pre-empt the field relating to the retail sales of drugs and proprietary medicines in the several states. LoBlaw, Inc. vs. New York State Board of Pharmacy, 1960, 202 N.Y.S. 711.

In connection with the Federal Food, Drug and Cosmetic Act the Supreme Court has heretofore held that Congress has the right not only to pass laws which regulate legitimate commerce among the states and with foreign nations but has full power to keep the channels of such commerce free from the transportation of illicit or harmful articles, to make such as are injurious to the public health, outlaws of such commerce and bar them from the facilities and privileges thereof. McDermott vs. Wisconsin, 228 U.S. 115. This being a law designed to protect the consumer from mislabeled foods and drugs and informing purchasers as to what they were buying, it is absurd to contend that state tort law cannot be applied where the labels or package insert either fails to properly inform the ultimate consumer as to any risk associated with the use of the product or seeks to conceal the risk from the public based upon the premise that a greater number will benefit from its use than will be permanently paralyzed as a result of submitting to inoculation without knowledge of the controversial risk which is unquestionably established as being an inheritant characteristic of the drug or vaccine. Nowhere in the Act did Congress attempt to limit the tort liability of the manufacturer for injuries incurred because the product had been labeled, either properly or improperly, under the Act.

The Act itself sets out what labeling is improper. It further provides for criminal liability for improper labeling. It does not say that unless the product be shown to be improperly labeled, there can be no tort liability with respect to its use. It does not say that the sole remedy for violation of the Act is by criminal proceedings, nor does it in any way give any manufacturer or health official the right to place a vaccine in the channels of commerce which has a known risk connected with its time of use or its actual use, simply because its use would benefit more people than it would harm, without making that risk known to the person who will either benefit or suffer from its use.

Mention has been made in the Petition that it has not been and cannot be alleged that the labeling which Petitioner provided with its trivalent polio vaccine was in any way false or misleading, and that it was developed with the approval of the Federal officials. The actual testimony of Dr. Mahlon Bierly, Executive Assistant to the President of Wyeth Laboratories, in the trial of the case was that he prepared the package insert and the record is devoid of any evidence that it was approved by any federal agency. Cross-examination of Dr. Bierly revealed that the package insert was materially lacking in many respects. The only reference to the seasonal limitation was "polio virus vaccine, live, oral, preferably should be administered during the non-polio season". As to what he meant by this provision, he stated that it should be interpreted by the local physician, wherever he may practice, and he admitted that if you were to assume that the physician had only read the insert, it would not furnish him with complete information, and for a doctor to give the vaccine with safety and full knowledge of its consequences and risks involved he must go further and do further research than what is contained in the package insert.

Thus, even though the Appellant admitted in Interrogatory No. 14 that the vaccine was a prescription drug, the information on the package insert was lacking in important respects, even to a medical doctor.

DISCUSSION OF SECOND POINT

The second question presented in the Petition is whether the Court of Appeals contravened the Public Health Policy of the State of Texas in its application of the Texas law by holding, in the face of statutorily expressed public policy of Texas, to the contrary.

In this regard, reference is made to Article 2.09, Immuni-

zation, Vernon's Education Code of Texas. This statute was enacted by the 62nd Legislature of Texas in 1971, and did not go into effect until May of 1971, approximately a year after Anita contracted polio. It could have no retoractive effect and certainly was not a part of the State's public policy in May of 1970. Even had it been the law, there is nothing in the statute which requires the child to be immunized by Sabin vaccine. She would have the choice under the law to follow the procedure utilized by Dr. Casso, wherein he first builds up the antibodies in children under one year of age by the use of Salk vaccine, and then feeds them Sabin vaccine after they have become one year of age.

The contention that public health authorities cannot play a meaningful role in administering prescription drugs used in immunization programs and will have serious repercussions because of the likelihood of communicable disease epidemic is therefore without basis. In the first place, we are only concerned with vaccines which carry with them a medically cognizable risk as was found by the jury in the case at bar; and in the second place, there is nothing which would prevent the health departments from following the procedures used by Dr. Casso and other McAllen pediatricians. The Sabin vaccine is not the only vaccine. The Salk vaccine was the first breakthrough in the control of poliomyelitis and there has never been any question raised regarding the efficacy of the Salk vaccine which is a killed virus vaccine. There was certainly no evidence introduced in the trial of the case that the procedure of first injecting with Salk vaccine when the child was under one year of age and following with Sabin vaccine after the antibodies had been built up confused or frightened the patients of Dr. Casso and the other pediatricians. If this procedure was successfully carried out in the private practice of medicine there is no reason why a similar procedure could not be used as a guideline for immunization programs on a State level.

The Petitioner places a great deal of reliance on the case

of Gravis vs. Parke-Davis & Co., 502, SW 2d 863 (Tex. Civ. App. Corpus Christi 1973), which was fully considered and discussed by the Circuit Court. This case is not in point. While it is a products liability case, it involves a fact situation whereby Mrs. C. K. Gravis underwent an initial examination in an emergency room in the hospital at Alice, Texas, and subsequent examinations and tests necessitated an exploratory operation. On October 24, 1963, she was administered a spinal anesthetic containing three different drugs. An intestinal obstruction was found and corrected. Later, after she had been moved back to her room Mrs. Gravis felt abnormal and couldn't move her legs.

Mrs. Gravis brought suit against Parke-Davis & Co., Winthrop Laboratories, Inc. and Sterling Drug Co. for personal injuries sustained by Mrs. Gravis. The case was tried before a jury; however, at the conclusion of the plaintiff's case the drug company moved for an instructed verdict or in the alternative to withdraw the case from the jury and render judgment as a matter of law. The motion was granted by the trial court on the basis that there was no evidence that the drugs were impure or defective. All of the evidence indicated to the contrary. Neither did the plaintiff rule out all of the other possible causes of the injuries which could establish substantially, at least, that the defective drug was the only cause * * * evidence on the critical issue of the existence of a defect in the drugs was not established.

While at this point the case was disposed of the Court went ahead to discuss by way of dicta that "We believe that it was unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient. Once the physician has been warned, the choice of which drugs to use, and the duty to explain the risks involved, is his. These drugs were manufactured for administration only by a physician or other authorized person. Generally speaking, only a physician would understand the propensities and dan-

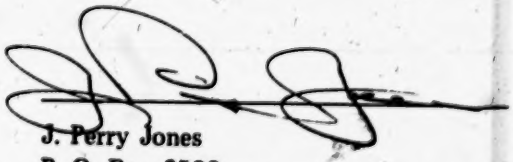
gers involved. The doctor is a learned intermediary between the manufacturer and the ultimate consumer."

There is no question but that there is a distinct difference between the responsibility of a drug manufacturer to warn of any risks associated with the sale of over-the-counter drugs and the warning which the ultimate consumer is entitled to when he has a face-to-face meeting with his physician. In such cases where there is a face-to-face meeting between the physician and the patient the manufacturer need not specifically warn each and every patient. While in the aforementioned Gravis-Parke-Davis & Co. case there was failure of proof that the drugs were impure or defective, all of the drugs and procedures used were administered personally by the physician who has long been held to be the learned intermediary between the manufacturer and the ultimate consumer. As stated in the Petition for Writ of Certiorari, a different panel of the Fifth Circuit has held that a physician in such position is not required to inform his patients of all risks involved in the treatment offered. He must act only as would a reasonable medical practitioner in the same circumstances. Karp vs. Cooley, 493 F. 2d 408 (5th Cir. 1974).

CONCLUSION

For the reasons stated, the Petition for Writ of Certiorari should be denied and the opinion of the United States Court of Appeals for the Fifth Circuit should be affirmed.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that on this the____ day of November, 1974, I mailed, certified mail, return receipt requested, two copies of Respondent's brief to Attorneys Clifford, Warnke, Glass, McIlwain, Finney & Spradlin, 815 Conneciticut Avenue, N. W., Washington, D. C. 20006, and to Attorneys Eberle, Berlin, Kading, Turnbow, Gillespie & McKlveen, 300 North Sixth Street, Post Office Box 1368, Boise, Idaho 83701.

J. Perry Jones